

EASTERN DISTRICT OF WISCONSIN  
GREEN BAY DIVISION

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ESTATE OF MARIAN A. MARKS,  
by CATHY DELVEAUX, Personal Representative,  
and CATHY J. DELVEAUX, Individually,  
and  
CHERYL MARKS MURPHY,

Plaintiffs,

ALEX M. AZAR II, SECRETARY of the  
DEPARTMENT OF HEALTH AND HUMAN SERVICES,  
and  
NETWORK HEALTH INSURANCE CORPORATION,

Involuntary Plaintiffs,

v.

COUNTRY VILLA ASSISTED LIVING IN PULASKI, INC.,  
d/b/a COUNTRY VILLA ASSISTED LIVING PULASKI,  
COUNTRY VILLA ASSISTED LIVING LLC and/or  
COUNTRY VILLA ASSISTED LIVING,  
c/o CHAD READER,

ABC 1-5 INSURANCE COMPANIES,

COUNTRY VILLA ASSISTED LIVING, INC.,  
d/b/a COUNTRY VILLA ASSISTED LIVING PULASKI,  
COUNTRY VILLA ASSISTED LIVING LLC and/or  
COUNTRY VILLA ASSISTED LIVING,  
c/o CHAD READER,

and

DEF -1-5 INSURANCE COMPANIES,

Defendants.

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**NOTICE OF REMOVAL TO FEDERAL COURT**

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Defendants Country Villa Assisted Living in Pulaski, Inc., and Country Villa Assisted Living,

Inc., (“Defendants”) hereby remove Case No. 2022CV0154 from the Circuit Court for Brown County to the United States District Court for the Eastern District of Wisconsin pursuant to 28 U.S.C. §§ 1331, 1367, 1441 and 1446 on the following grounds:

### **STATEMENT OF THE CASE**

1. On February 8, 2022, Plaintiffs filed a Complaint in Brown County Circuit Court, captioned as *The Estate of Marian A. Marks, et al. v. Country Villa Assisted Living in Pulaski, Inc., et al.*, Case No. 2022CV1054 (the “State Court Action”). A copy of the Complaint is attached hereto as Exhibit A.

2. Country Villa Assisted Living in Pulaski, Inc., and Country Villa Assisted Living, Inc., (Collectively, “Country Villa Assisted Living”) were served with the Complaint on February 28, 2022.

3. The Complaint alleges negligence as plaintiff’s cause of action. Plaintiff’s contention is that Country Villa Assisted Living failed to take sufficient precautions in the early days (March 2020-May 2020) of the COVID-19 pandemic. In the Complaint, plaintiffs allege 18 different theories of negligence, including but not limited to:

- a. “Failing to institute, develop, and/or implement adequate and or necessary COVID-19 Emergency Plans”;
- b. “Failing to cease communal dining and group activities”;
- c. “Failing to ensure Defendants’ staff members that were exhibiting signs and symptoms of Covid-19, awaiting COVID-19 test results, and/or positive for COVID-19 immediately stopped working”;
- d. “failing to utilize, provide, ensure, and or/obtain a sufficient supply of PPE”;
- e. “failing to develop, implement, and/or arrange for necessary, adequate, and/or safe strategies to optimize PPE, PPE practices. . . and/or other PPE measures”; and
- f. “failing to adequately hire, retain, and/or provide a sufficient number of

competent and qualified personnel”;

4. The Defendants dispute these allegations, and maintain Country Villa Assisted Living undertook significant measures to prevent a Covid-19 outbreak including optimizing, administering and using PPE, testing residents, testing staff, isolating residents to their living quarters, preventing visitors from entering the facilities, and further measures that were consistent with recommendations in the very early days of the pandemic.

5. The Plaintiffs seek 1) compensatory damages; 2) punitive damages 3) a hearing on subrogation interest due to Network Health Insurance Corporation; and 4) statutory fees, interest, costs and disbursements.

**ALL PROCEDURAL REQUIREMENTS HAVE BEEN SATISFIED**

6. Pursuant to 28 U.S.C. § 1446 and Civil L. R. 8, a true and correct copy of all of the process, pleadings, orders, and documents from the State Court Action which have been served upon the Defendants are being filed with this Notice of Removal.

7. This Notice of Removal has been filed within 30 days of the date that Country Villa Assisted Living was served with the Summons and Complaint in this matter. Removal is therefore timely in accordance with 28 U.S.C. § 1446(b). Concurrent with the filing of this Notice or promptly thereafter, this Notice of Removal is being served on all other parties pursuant to 28 U.S.C. §1446(d).

8. As of the date of this Notice, there have been no orders issued by the Brown County Circuit Court.

9. Venue is proper in this Court pursuant to 28 U.S.C. § 1441(a) and 1446(a) because the U.S. District Court for the Eastern District of Wisconsin is the federal judicial district embracing the Brown County Circuit Court where the State Court Action was originally filed. However, defendants reserve all rights to contest venue as improper under 42 U.S.C. §247d-6d( e)(1).

**ARGUMENT AND CITATION TO AUTHORITY**

## **FEDERAL QUESTION JURISDICTION UNDER 28 U.S.C. § 1331, 14441(a)**

10. This Court has jurisdiction over the matter under 28 U.S.C. § 1331 because there is a federal question presented under the Covid-19 immunity provisions under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e (the “PREP Act”) and the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198 (Mar. 17, 2020), *amended by* 85 Fed. Reg. 21012 (Apr. 15, 2020), 85 Fed. Reg. 35100 (June 8, 2020), 85 Fed. Reg. 52136 (Aug. 24, 2020), 85 Fed. Reg. 79190 (Dec. 9, 2020), 86 Fed. Reg. 7872 (Feb. 2, 2021), 86 Fed. Reg. 9516 (Feb. 16, 2021) *as corrected by* 86 Fed. Reg. 10588 (Feb. 22, 2021), *and* 86 Fed. Reg. 14462 (Mar. 16, 2021), 86 Fed. Reg. 41977 (Aug 4, 2021), 87 Fed. Reg. 982 (Jan. 7. 2022) (herein “the Declaration”). Therefore, the Complaint asserts a claim “arising under” federal law within the meaning of § 1331.

11. Although the Complaint does not, on its face, rely upon any provision of federal law, federal question jurisdiction is proper under the doctrine of complete preemption. The PREP Act meets the criteria for complete preemption by broadly preempting all state law claims within its ambit and by providing an exclusive set of federal remedies.

12. Federal question jurisdiction is also proper under the “substantial federal question” doctrine because the Complaint sets forth causes of action that necessarily turn on disputed questions of federal law and removal would further the congressionally mandated division of state and federal interests under the PREP Act. Pursuant to its authority under the PREP Act, The United States Department of Health and Human Services (“HHS”) has declared that any claim falling within the PREP Act presents a “substantial federal question” and is therefore removable. *See* 85 Fed. Reg. 79190.

13. Here, Plaintiff’s Complaint falls under the PREP Act because it asserts a claim for loss “caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure.” Therefore, federal question jurisdiction exists over the claim.

I. **The Doctrine of “Complete Preemption” Applies to Any Claim Preempted Under the PREP Act Because the PREP Act (1) Expressly Preempts State Law Claims for Loss, and (2) Provides an Exclusive Set of Federal Remedies**

14. Plaintiff’s claim is removable under federal question jurisdiction because the PREP Act simultaneously preempts Plaintiff’s claim and provides an exclusive federal cause of action for all such claims.

15. Federal question jurisdiction exists when

“a federal statute wholly displaces the state-law cause of action through **complete pre-emption**. . . this Court has found complete pre-emption [when] . . . the federal statutes at issue **provided the exclusive cause of action** for the claim asserted and also **set forth procedures and remedies governing that cause of action.**” *Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003).

16. Circuit and district courts considering the issue have found “complete preemption” where a federal statute (1) expressly preempts state law and (2) creates an exclusive federal remedy for preempted state claims. *See, e.g., Beneficial Nat. Bank v. Anderson*, 539 U.S. 1, 8 (2003) (involving a situation where the National Bank Act preempted state usury law). *In re WTC Disaster Site*, 414 F.3d 352, 380 (2d Cir. 2005); *Spear Marketing, Inc. v. Bancorp South Bank*, 791 F.3d 586 (5th Cir. 2015); *Nott v. Aetna U.S. Healthcare, Inc.*, 303 F.Supp.2d 565 (E.D.Pa. 2004).

17. The PREP Act satisfies both prongs of this analysis. First, the PREP Act preempts state law to the extent that it would deprive an individual or entity of the immunity it confers. Under 42 U.S.C. § 247d-6d(a)(1), a “covered person” is afforded broad immunity “from suit and liability under Federal and State law” for “all claims for loss caused by, arising out of, relating to, or resulting from” the “administration” or “use” of a “covered countermeasure” if the Secretary of the Department of Health and Human Services issues a declaration to that effect—which it has. Moreover, under 42 U.S.C. § 247d-6d(b)(8), state law that “is different from, or in conflict with, any requirement applicable under this section [§ 247d-6d] and relates to . . . the administration by qualified persons of the covered countermeasure” is expressly preempted. This language would include

enforcement of common law through a state tort system. Therefore, under the Declaration, the PREP Act broadly preempts a wide array of state law claims.

18. Second, the PREP Act establishes an exclusive federal cause of action for any claim preempted, and also establishes the procedures applicable to such actions. Under 42 U.S.C. § 247d-6d(d)(1) “the sole exception to the immunity from suit and liability of covered persons ... shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct.” Claims for “willful misconduct” are subject to several heightened pleading requirements. § 247d-6d(e)(1)-(4). Moreover, any action for “willful misconduct” “shall be filed and maintained only in the United States District Court for the District of Columbia,” and must be brought before a three-judge panel. § 247d-6d(e)(1), (e)(5). The PREP Act also establishes a host of other procedural requirements for such claims, including limitations on damages and limited discovery rights. *See generally* § 247d-6d(e).

19. On January 8, 2021, HHS issued an Advisory Opinion expressly stating that the PREP Act triggers the doctrine of “complete preemption,” including in claims of negligent infection control within an adult care facility. HHS, Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021).<sup>1</sup> Additionally, nearly every PREP Act Declaration made in the context of COVID-19 includes language stating the PREP Act is a complete preemption statute. *See* The Declaration.

20. Since the onset of the COVID-19 pandemic, several district courts have addressed whether the PREP Act is the type of statute that triggers complete preemption. To date, two district courts have recognized that the PREP Act triggers complete preemption. *See Garcia v. Welltower OpCo Group, LLC*, No. 8:20-cv-02250 (C.D. Cal. Feb. 10, 2021); *Rachal v. Natchitoches Nursing & Reab. Ctr.*,

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<sup>1</sup> Available at: <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf>.

No. 1:21-cv-334, at \*N.3 (W.D.L.A. Apr. 30, 2021). Both of these cases involve allegations of improper infection control within an adult care facility.

21. In *Garvia*, the plaintiff alleged that the defendant facility negligently failed to prevent the spread of COVID-19, resulting in death to the plaintiff's decedent. *Garvia*. at 2-3. In denying the plaintiff's motion to remand, the *Garvia* court recognized that the PREP Act provided "sweeping immunity" from suit and liability under federal and state law while providing a trade-off of "exclusive" remedies. *Id.* at 5, 6. The court then recognized the various authorities issued by HHS addressing the scope of the PREP Act in response to the very district court orders that the plaintiff had cited to in support of remand. *Id.* at \*10, *citing Chevron, Inc. v. NDRC, Inc.*, 467 U.S. 837, 843 (1984), *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), and *United States v. Mead Corp.*, 533 U.S. 218, 220 (2001); *id.* at \* 11 ("OGC affirmed that the PREP Act is a complete preemption statute and clarified the scope of the Act relative to the ongoing pandemic."), *citing* Advisory Opinion 21-01 ; *see also id.* at n. 3 ("*Chevron* is not black and white, and the Supreme Court has made clear that courts are not faced with an option of complete deference or none at all.").

22. The *Garvia* court therefore concluded that in light of the recent authority from HHS:

[O]nly instances of nonfeasance, i.e., where "defendant's culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person" would complete preemption not attach. Total inaction, therefore, would not be covered by the PREP Act.

*Id.* at \* 11 (*citing* Advisory Opinion 21-01).

23. The *Garvia* court acknowledged that its holding deviated from prior orders granting remand, but explained that those orders were issued **before** Advisory Opinion 21-01 clarified the scope of PREP Act immunity.<sup>2</sup> *Garvia*, 8:20-cv-02250-JVS-KESx at \*9-10. Likewise, the court

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<sup>2</sup> *Jackie Saldana v. Glenhaven Healthcare LLC*, No. CV205631FMOMAAX, 2020 WL 6713995 at \*2 (C.D. Cal. Oct. 14, 2020) (*citing City of Oakland v. BP PLC*, 969 F.3d 895, 907 (9th Cir. 2020); *Martin v. Serrano Post Acute LLC*, 2020 WL 5422949, \*1-2 (C.D. Cal. 2020).

rejected the holdings of the *Dupervil* court (addressed below) and other district courts that issued remand orders after Advisory Opinion 21-01, but which declined to follow that Opinion. *Id.* at \*10, n. 2.

24. In *Rachal*, which involved similar allegations to those at issue in *Garvia*, the court concluded that the PREP Act satisfied all criteria for complete preemption because it (1) contained a civil enforcement provision that replaces and protects an analogous area of state law; (2) contained a specific jurisdictional grant to the federal courts to enforce the same; and (3) contained a clear congressional intent that such jurisdiction would be exclusive. It also found the PREP Act particularly analogous to another statute that was found to establish complete preemption because both statutes (1) create an administrative no-fault compensation fund; (2) provide broad immunity from suit for certain entities/individuals; (3) create an exclusive federal cause of action for certain residual claims; and (4) confer exclusive jurisdiction over such causes of action unto a specified federal venue. *Rachal*, at N. 3, citing *In re WTC Disaster Site*, 414 F.3d 352 (2d Cir. 2005).

25. The *Rachal* court also observed that the distribution of PPE within an adult care facility constituted administration of a covered countermeasure under the PREP Act. It reasoned that HHS, in Advisory Opinion 21-01, “took a broad view of the applicability of the PREP Act as it relates to claims against nursing homes and other healthcare providers for failing to provide sufficient personal protective equipment (“PPE”) or adequate training on the use of PPE [and] rejected the position adopted by some courts that if a covered countermeasure were not used, then there is no PREP Act immunity.” *Rachal* at \* 11. Accordingly, it concluded that, consistent with the OGC’s Opinion, only the complete “failure to make any decisions whatsoever” would bring a claim of non-administration outside of the scope of complete preemption under the PREP Act. *Id.*

26. In contrast to *Garvia* and *Rachal*, several other district courts have granted remand of cases removed under the PREP Act. Defendants submit that these remands were made in error for

various reasons, including decisions predating the more recent HHS authority stating that the PREP Act triggers complete preemption, erroneous readings of the statutes, and failing to afford the proper *Chevron* deference to advisory opinions. *See e.g., Baskin v. Big Blue Healthcare*, No. 2:20-cv-2267 (D.Ka Aug. 19, 2020); *Stone v. Long Beach Healthcare Ctr.*, No. 2:21-cv-00326 (C.D.Ca Mar. 26, 2021).

27. Accordingly, the PREP Act meets both criteria for “complete preemption.” It expressly preempts a wide array of state law tort claims. It also provides an exclusive federal cause of action for any claim preempted. Therefore, federal question jurisdiction exists over any claim falling under the preemptive purview of the PREP Act.

**II. Any Claim Involving the Interpretation of the PREP Act is Removable Under the “Substantial Federal Question” Because HHS has Expressly Declared that the Application of the PREP Act is a “Substantial Federal Question.”**

28. Removal is also proper because Plaintiff’s Complaint presents an “substantial federal question.” *See Gunn v. Minton*, 568 U.S. 251, 258 (2013) *citing Grable & Sons Metal Prods. v. Darue Engineering & Mfg.*, 545 U.S. 308, 314 (2005).

29. In *Grable*, the Supreme Court set forth a two-step process for determining whether such a claim is removable: First, the state law claim must necessarily raise a federal issue, actually disputed and substantial. Second, federal courts must be able to entertain the state law claims, “without disturbing a congressionally approved balance of state and federal judicial responsibilities.” *Id.* at 314.

30. On December 9, 2020, HHS amended the Declaration to expressly provide that the PREP Act triggered the “substantial federal question” doctrine under *Grable*. 85 Fed. Reg. 79190 (Dec. 9, 2020). In the Preamble to that amendment, the Secretary explains:

The Secretary **makes explicit** in Section XI that **there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response** to the COVID-19 pandemic among federal, state, local, and private-sector entities...

85 Fed. Reg. at 79194 (emphasis supplied). Then, in Section XI, the Secretary formally declares:

COVID-19 is a global challenge that requires a whole-of-nation response. **There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mfg.*, 545 U.S. 308 (2005).**"

85 Fed. Reg. at 79197-98 (emphasis supplied), *citing* 42 U.S.C. § 247d-6d(b)(7).

31. The above statements show the Secretary intended for removal jurisdiction to extend to any claim that involves the "interpretation of the PREP Act," in order to ensure a more uniform application of a statute that was integral to the Secretary's response to the COVID-19 pandemic. The PREP Act provides immunity from suit, which means that adjudication on the issue of applicability should be completed by federal courts and not state courts for the purposes of uniformity.

32. Notably, under the PREP Act, the language of this Declaration is to be conclusive on all issues regarding the invocation of the Act. *See* 42 U.S.C. § 247d-6d(b)(7) ("No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."). At the very least, however, Section XI should be afforded *Chevron* controlling weight because it is an agency's interpretation of the very statute it is charged with administering, because congress has not spoken expressly on the issue, because it involves an area of knowledge within the expertise of the Secretary, and because it the Secretary's delegated authority to lead the nation's response to the COVID-19 pandemic. *See, e.g. Cuozzzo Speed Tech., LLC v. Lee*, 136 S.Ct 2131, 2142 (2016) ("where a statute leaves a 'gap' or is 'ambigu[ous],' we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute.") *citing* *U.S. v. Mead Corp.*, 533 U.S. 218, 229 (2001); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

33. Notably, under the PREP Act, the language of this Declaration is to be conclusive on all issues regarding the invocation of the Act. *See* 42 U.S.C. § 247d-6d(b)(7) ("No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."). At the very least, however, Section XI

should be afforded *Chevron* controlling weight because it is an agency's interpretation of the very statute it is charged with administering, because congress has not spoken expressly on the issue, because it involves an area of knowledge within the expertise of the Secretary, and because it the Secretary's delegated authority to lead the nation's response to the COVID-19 pandemic. *See, e.g. Cuozzo Speed Tech., LLC v. Lee*, 136 S.Ct 2131, 2142 (2016) ("where a statute leaves a 'gap' or is 'ambigu[ous],' we typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute.") *citing* *U.S. v. Mead Corp.*, 533 U.S. 218, 229 (2001); *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

34. Therefore, any claim that implicates the PREP Act is removable under the fourth amendment to the Declaration and the subsequent authority issued by HHS, both of which expressly invoke the "substantial federal question" doctrine of *Grable*.

### **III. Plaintiff's Claim Falls Under the PREP Act Because it "Relates to" the Administration and Use of Covered Countermeasures by a Covered Person**

35. Under the PREP Act, there is preemption of any state law cause of action against a covered person that asserts "claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure" if the Secretary of HHS issues a declaration to that effect. 42 U.S.C. § 247d-6d(a)(1). In response to COVID-19, the Secretary of HHS issued the Declaration, which provided immunity under the PREP Act to any "covered person" who engaged in any "recommended activities," including the "distribution, administration, and use" of "covered countermeasures." 85 Fed. Reg. 15201.

36. The gravamen of Plaintiff's claim is that the Defendants' actions, or lack of actions, taken in response to the COVID-19 pandemic were ineffective to prevent the spread of COVID-19 throughout the facility, causing Marian Marks to contract the disease. Because such a claim necessarily "relates to" and "arises out of" a covered person's "administration" and "use" of products meeting

the definition of “covered countermeasures,” it falls under the preemptive scope of the PREP Act and triggers removal jurisdiction.

*A. Defendants are “Covered Persons” under the PREP Act*

37. Under the PREP Act and HHS’s Declaration, the phrase “covered person” includes: “‘program planners,’ ‘qualified persons,’ and their officials, agents, and employees”; any person “authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction ... to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors”; “any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act”; and “any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.” 85 Fed. Reg. at 15201-02.

38. The phrase “qualified person” has a broad definition that includes any “licensed health professional or other individual who is authorized to prescribe, administer, or dispense [covered] countermeasures under [applicable state law]”; any “person [so] authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction ... and their officials, agents, employees, contractors and volunteers ...”; and any person so-authorized under an “Emergency Use Authorization in accordance with Section 564 of the FD&C Act” or “in accordance with Section 564A of the FD&C Act.” 42 U.S.C. § 247d-6d(i)(8). The phrase “Authority Having Jurisdiction,” in turn, means the “public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, state, or federal boundary lines) or functional (e.g., law enforcement, public health) range of sphere or authority.” 85 Fed. Reg. at 15202. The term “distributor” is also broadly (and circuitously) defined as

“a person or entity engaged in the distribution of drugs, biologics, or devices ....” 42 U.S.C. § 247d-6d(i)(3).

39. Similarly, the phrase “program planner” is broadly defined as a person or entity who: “supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with [the Secretary’s declaration].” 42 U.S.C. § 247d-6d(i)(6) (emphasis supplied); see also, HHS Advisory Opinion 21-01. The Preamble to the Declaration explains that a “private sector employer or community group or other ‘person’ can be a program planner when it carries out the described activities.” 85 Fed. Reg. at 15202.

40. Finally, the phrase “person,” which is used repeatedly throughout these and other definitions, includes an “individual, partnership, corporation, association, entity, or public or private corporation ...” 42 U.S.C. § 247d-6d(i)(5).

41. Notably, HHS has advised that senior living communities are “covered persons” under the PREP Act as both “qualified persons” and “program planners.” *See* Charrow, Response Letter (Aug. 14, 2020) (Exhibit B). In its Response Letter, HHS states: “a senior living community meets the definition of a ‘program planner’ to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including by ‘provid[ing] a facility to administer or use a Covered Countermeasure in accordance with’ the Declaration.” *Id.* at 2. The Response Letter further states that senior living communities would be “qualified persons” if they were authorized by a state or local public health official to administer or use covered countermeasures. *Id.* at N. 3.

42. Here, Plaintiff alleges in the Complaint that Defendants were licensed under state law to operate an assisted living center. Plaintiff further alleges that, by virtue of such licensure, Defendants had an affirmative obligation to take affirmative measures to prevent the spread of COVID-19 in the facility, including the administration and optimization of PPE and COVID-19 testing as alleged in the Complaint. Therefore, Plaintiff is effectively estopped from denying that Defendants were authorized under state law to administer or use covered countermeasures for that very purpose. As such, Defendant is a “qualified persons” under the PREP Act.

43. Moreover, as set forth in the affidavit of Chad Reader, the staff at Country Villa Assisted Living developed policies and procedures for the use and administration of various covered countermeasures for the purposes of infection control, as well as a facility to administer COVID-19 tests. This systematic administration and use of covered countermeasures is precisely the type of activity that the definition of “program planner” encompasses. Therefore, Defendant is a “program planner” under the PREP Act.

44. Therefore, Defendant is a “covered persons” within the meaning of the PREP Act and the Declaration.

***B. Plaintiff's Claims Relate to “Covered Countermeasures” under the PREP Act***

45. As set forth in the Declaration, the term “covered countermeasure” is defined as follows:

[(1)] ***any*** antiviral, ***any*** other drug, ***any*** biologic, ***any*** diagnostic, ***any*** respiratory protective device, ***any other device***, or any vaccine, ***used***

- a. ***to treat, diagnose, cure, prevent, or mitigate COVID-19***, or the transmission of SARS-CoV-2 or a virus mutating therefrom, ***or***
- b. ***to limit the harm that COVID-19***, or the transmission of SARS-CoV-2 or a virus mutating therefrom, ***might otherwise cause***; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product.

\* \* \*

[provided the product can also be classified as one or more of the following:] “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or any respiratory protective device approved by NIOSH under 42 CFR part 84 ...

85 Fed. Reg. at 35102 (emphasis supplied); *see also* 42 U.S.C. § 247d-6d(i).

46. Thus, while the number of products meeting the definition of “covered countermeasures” are “too numerous to list,” it includes (1) diagnostic products such as COVID-19 tests; (1) products used to reduce the spread of COVID-19, such as PPE, N-95 respirators, and hand sanitizers; (3) products used to monitor individuals with confirmed or suspected COVID-19, such as thermometers and pulse oximeters; and (4) drugs, devices, and therapeutics administered to individuals with confirmed or suspected COVID-19, such as supplemental oxygen. *See* Advisory Opinion 20-01; 21 CFR §§ 878.4040 (surgical apparel), 880.6250 (non-powdered patient examination gloves), 880.6256 (examination gowns); 21 CFR §§ 880.2200, 880.2900, 880.2910, 880.2920, 880.2930 (thermometers); 21 C.F.R. § 870.2700 (Pulse oximeters); 21 C.F.R. §§ 870.4100, 868.5340, 868.5570 (non-rebreather masks and nasal cannulas for administration of supplemental oxygen); 82 Fed. Reg. 60474 (final rule for health care antiseptic products); 84 Fed. Reg. 14847 (final rule for consumer antiseptic products); FDA Combating COVID-19 with Medical Devices, FDA<sup>3</sup> (listing Emergency Use Authorization for *inter alia*, COVID-19 test kits, certain types of PPE, respiratory protective devices, therapeutics, and drugs).

47. Here, Plaintiff’s Complaint places directly into issue Defendants’ use and administration of many such products. For example, the Complaint states the defendants:

a. “failed to ensure PPE was immediately available outside of resident rooms”;

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<sup>3</sup> Available at: <https://www.fda.gov/media/136702/download>.

b. “Fail[ed] to ensure Defendants’ staff members that were exhibiting signs and symptoms of Covid-19, awaiting COVID-19 test results, and/or positive for COVID-19 immediately stopped working”;

c. “fail[ed] to utilize, provide, ensure, and or/obtain a sufficient supply of PPE”;  
and

d. “failing to develop, implement, and/or arrange for necessary, adequate, and/or safe strategies to optimes PPE, PPE practices. . . and/or other PPE measures.”

48. Therefore, Plaintiff’s claim that the infection control within the facility was negligent, as generally outlined above, “relates to” products that meet the definition of “covered countermeasures” under the PREP Act and the Declaration.

***c. Plaintiff’s Claims Relate to the “Administration” and “Use” of “Covered Countermeasures” under the PREP Act***

49. The PREP Act applies to any claim for injury that is “caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure ....” 42 U.S.C. § 247d-6d(a)(1). The Declaration, in turn, provides PREP Act immunity for all “recommended activities,” which include the “use” or “administration” of covered countermeasures. 85 Fed. Reg. at 15201.

50. Plaintiff’s claim places into issue *how* Defendants “administered” and “used” “covered countermeasures” for purposes of infection control. It therefore falls under the purview of the PREP Act because it “relates to” and “arises out of” the “administration” and use of covered countermeasures.

51. Here, Plaintiff’s claim, “relates to” and “arises out of” Defendants’ “use” and “administration” of covered countermeasures within the facility for purposes of infection control. The allegations of the complaint relate to among other actions, the manner in which Defendants used and distributed PPE within the facility to control the spread of COVID-19, the manner in which

Defendants screened individuals for COVID-19 symptoms, the manner in which Defendants, and the manner in which Defendants implemented a system for testing individuals for COVID-19.

52. Moreover, the staff within the facility were regularly using and administering various “covered countermeasures” on a daily basis as an integral part of their infection control policies.

53. Plaintiff does not allege specifically how decedent was exposed to COVID-19. Rather, Plaintiff merely alleges that all of the infection control measures within the facility including those outlined in the Complaint were deficient in preventing the spread of COVID-19, and that this caused injury. Therefore, Plaintiff’s Complaint places into issue all activities Defendants took with respect to infection control within the facility.

54. Therefore, Plaintiff’s claim “arises out of” and “relates to” Defendants’ “administration” and “use” of “covered countermeasures, and falls within the scope of the PREP Act.

**C. EXCLUSIVE ORIGINAL JURISDICTION UNDER 42 U.S.C. § 247d-6d(e)(1)**

55. Defendants maintain that Plaintiff’s pleadings do not assert any legally cognizable cause of action because the claim pleaded “relates to” and “arises out of” Defendants’ “administration” and “use” of “covered countermeasures” for the purposes of infection control within the facility, and therefore fall under the preemptive purview of the PREP Act.

56. However, Defendants further assert in the alternative that, to the extent Plaintiff’s pleadings are construed to assert any viable cause of action, the sole cause of action they could assert would be a claim for “willful misconduct” under the PREP Act. *See* 42 U.S.C. § 247d-6d(d)(1).

57. Under the PREP Act, the District Court for the District of Columbia has exclusive jurisdiction for claims of “willful misconduct” brought under 42 U.S.C. § 247d-6d(e)(1), which states that “[a]ny action under [42 U.S.C. § 247d-6d(d)] shall be filed and maintained only in the United States District Court for the District of Columbia.”

58. Therefore, to the extent that the Complaint asserts any cognizable cause of action, that cause of action raises a federal question over which the District Court for the District of Columbia has exclusive jurisdiction pursuant to an act of congress, and this matter is removable under § 247d-6d(e)(1).

59. Notwithstanding, Defendants reserve all rights to contest the validity of any purported claim for “willful misconduct,” including all procedural requirements, pleading requirements, and venue requirements set forth in § 247d-6d(e). Upon removal, Defendants intend to move for dismissal under the same and reserve the right to request transfer to the District Court for the District of Columbia.

#### **D. SUPPLEMENTAL JURISDICTION UNDER 28 U.S.C. § 1367**

60. When a case is removed based on federal question jurisdiction or federal officer jurisdiction, under 28 U.S.C. § 1367, a district court has supplemental jurisdiction “over all other claims that are so related ... that they form part of the same case or controversy.”

61. Here, all of the conduct alleged in the Complaint arises from the same set of transactions and occurrences. Therefore, to the extent that any cause of action contained within the Complaint does not fall within the federal question, Defendants request that the Court exercise its supplemental jurisdiction over such residual causes of action pursuant to 28 U.S.C. § 1367.

**WHEREFORE**, having shown that this case is properly removable, Defendant provides notice pursuant to 28 U.S.C. § 1446 that the Action pending in Brown County Circuit Court of the State of Wisconsin, Case No. 2022CV0154 is removed to the United States District Court for the Eastern District of Wisconsin and respectfully requests that this Court exercise jurisdiction over this case.

Respectfully submitted this 30 day of March, 2022.

**CORNEILLE LAW GROUP, LLC**

*Electronically signed by: Mark T. Budzinski*

Mark T. Budzinski

State Bar No. 1036103

David J. Pliner

State Bar No. 1000394

Defendants Country Villa Assisted Living in Pulaski,  
Inc., and Country Villa Assisted Living, Inc.

Address:

615 S. Monroe Ave  
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Ph: 920-884-2321  
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**CERTIFICATE OF SERVICE**

The undersigned hereby affirms and certifies that a copy of the foregoing document was deposited in the United States Mail this 30 day of March, 2022 to:

Katherine E. Metzger  
Pitman, Kalkhoff, Sicola & Dentice, S.C.  
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**CORNEILLE LAW GROUP, LLC**

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